

REMARKS

Claims 58-67 are pending. Claims 58, 62, and 63 have been amended to more specifically point out what applicants regard as the invention. Support for these amendments may be found *inter alia* in the specification. Applicants submit that these amendments raise no issue of new matter. Thus, claims 58-67 remain pending and under examination.

In view of the arguments set forth below, applicants maintain that the Examiner's rejections made in the August 26, 2003 Office Action have been overcome, and respectfully request that the Examiner reconsider and withdraw same.

Rejections Under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 58-67 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Specifically, the Examiner rejected claim 58 as allegedly indefinite in reciting the term "EPMI-hCG" because acronyms or abbreviations must be fully defined and recited at least once in a set of claims.

The Examiner also rejected claim 58 as allegedly vague and indefinite because in the Examiner's opinion it is unclear as to whether the first antibody or the EPMI-hCG is recognized by the B152 antibody.

In response, applicants have inserted the definition of "EPMI-hCG" into claim 58 and amended the claims in order to clarify the point that the first antibody binds to the EPMI-hCG, which EPMI-hCG is recognized by the B152 antibody.

In view of the above remarks, applicants maintain that claims 58-67 satisfy the requirements of 35 U.S.C. §112, second paragraph.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 58-67 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to allow one skilled in the relevant art to which it pertains to make and/or use the invention commensurate in scope with the claims.

Applicants understand the Examiner's argument to be based upon two allegations, namely that (1) the specification fails to provide an adequate written description of the antibody of the claimed methods and (2) without specific description of EPMI-hCG or the epitope to which the antibody binds, one of skill in the art would be unable to make and use the antibody in the claimed method.

In response, applicants maintain that no undue experimentation is required to make and use the antibody of the claimed methods for the reasons set forth in their March 13, 2003 Amendment. Specifically, applicants maintain (1) that the description in the prior art of the C5 hCG is sufficient to enable one of skill to make and use the invention as claimed; and (2) that neither the chemical structure of EPMI-hCG nor the epitope of EPMI-hCG that is recognized by the antibody of the claimed methods is required to make and use the invention.

The Examiner acknowledged that the level of skill in the art at the time of filing was such that production of antibodies against "well-characterized antigen[s], i.e.  $\alpha$ hCG,  $\beta$ hCG, FSH, [was] well known and conventional." Applicants point out that the working example provided in the specification, namely the B152 antibody, was produced against the "C5" hCG, which is an isoform of hCG excreted by a choriocarcinoma. Thus, the antibody used in the claimed invention binds both C5 hCG and EPMI-hCG. Applicants previously demonstrated that C5 was well-characterized, insofar as the source, purification, and structure of C5 were taught in the prior art (see page 10 of applicants' March 13, 2003 Amendment).

Applicants: O'Connor et al.  
Serial No.: 09/630,215  
Filed: August 1, 2000  
Page 8

Accordingly, in view of the recognized high level of skill in the art, particularly the conventional production of antibodies against well-characterized antigens, applicants maintain that the claimed invention is enabled by the instant specification and respectfully request the Examiner to withdraw her rejection thereto.

The Examiner also rejected claims 58-67 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants understand the Examiner's rejection to be based upon the following assertions: (1) applicants have provided only a single working example of an anti-EPMI-hCG antibody, namely B152; and (2) the claimed anti-EPMI-hCG antibody can not be defined by its binding function due to lack of characterization of EPMI-hCG itself.

In response to the Examiner's position, applicants reiterate that the antibody of the claimed methods binds to C5 hCG, as taught in the specification at page 31 lines 3-9, as well as to EPMI-hCG, and that C5 hCG was well-characterized in the prior art. Thus, applicants maintain that the antibody of the claimed methods can be characterized by its binding function. Moreover, applicants point out that "one species may adequately support a claim to a genus" and that "[w]hat constitutes a representative number is an inverse function of the skill and knowledge in the art." M.P.E.P. 2163 (II)(A)(3)(a)(ii). The Examiner has acknowledged that "antibody technology is a mature technology where the level of skill is high and advanced ..." Accordingly, applicants maintain that the working example provided by the specification is sufficient to exemplify the antibody of the claimed methods.

In view of the above remarks, applicants maintain that claims 58-67 satisfy the requirements of 35 U.S.C. §112, first paragraph.

Double Patenting Rejection

The Examiner rejected claims 58-67 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53, 59, 60, 65, 71, 72, and 77-82 of U.S. Serial No. 09/017,976, now U.S. Patent No. 6,500,627, for the reasons of record.

In response, applicants will submit a terminal disclaimer at such time as the instant claims are deemed allowed.

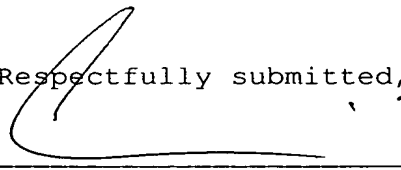
Summary

In view of the amendments and remarks made herein, applicants maintain that the claims pending in this application are in condition for allowance. Accordingly, allowance is respectfully requested.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



John P. White  
Registration No. 28,678  
Alan J. Morrison  
Registration No. 37,399  
Attorneys for Applicants  
Cooper & Dunham, LLP  
1185 Avenue of the Americas  
New York, New York 10036  
(212) 278-0400

<p>I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:</p> <p>Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450</p> <p>Alan J. Morrison Reg. No. 37,399</p> <p>Date 11/26/03</p>
---